AF/1653

PATENT

Attorney Docket No. **UM-03662**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Marc Peters-Golden *et al.*	
Serial No.:	09/291,656	Group No.: 1653
Filed:	03/03/1999	Examiner: K. Carlson
Entitled:	**Administration Of Products Of The 5-Lipoxygenase Metabolic Pathway To Enhance Antimicrobial Defense**	

REPLY BRIEF TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: August 16, 2005 By: _____
Traci E. Light

Sir or Madam:

Transmitted herewith is a Reply Brief with new arguments, pursuant to 37 CFR § 1.193, in Response to the Examiner's Answer mailed **June 16, 2005** in which new arguments were made.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: August 16, 2005 By: _____
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Marc Peters-Golden *et al.*
Serial No.: 09/291,656 Art Unit: 1653
Filed: 03/03/99 Examiner: K. Carlson
Entitled: **Administration Of Products Of the 5-Lipoxygenase Pathway**

REPLY BRIEF (37 CFR § 1.193) TO EXAMINER'S ANSWER MAILED JUNE 16, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Dated: 8/16/2005 By: _____
Traci E. Light

Madam:

On June 16, 2005, the Examiner mailed an Answer to Appellants' Brief wherein new arguments were made. *See* ¶ 11 of the Examiner's Answer. Pursuant to 37 CFR § 1.193, the Applicants hereby provide a Reply Brief wherein the new arguments are addressed.

Since the Reply Brief is filed within two months of the date of mailing of the Answer, the Reply Brief is timely. Nonetheless if there are any fees required and/or any required Petition for Extension of Time for filing this Reply Brief, they are dealt with in the accompanying **TRANSMITTAL OF REPLY BRIEF**.

ARGUMENT

The Examiner raises several new points of argument and reasserts old arguments. The Applicants provide argument below in rebuttal to the Examiner's new arguments. Moreover, this Reply Brief serves to clarify the Applicants' position on the Examiner's old arguments. In regards to other statements within the Examiner's Answer, not explicitly referred to herein, the Applicant's Appeal Brief is herein incorporated by reference.

I. Gosselin et al. Is Not Prior Art

A. The '059 Gosselin et al. Does Not Disclose A "Sterile Solution"

The Examiner has set forth a new argument. The Examiner maintains that Claims 22-25 and 27-37 are allegedly unpatentable under 35 U.S.C. 103(a) by Gosselin *et al.* (USP 5,789,441; '441 Gosselin et al.), by arguing that the now abandoned priority application (08/602,059; '059 Gosselin et al.) has "... support for sterile solutions of leukotrienes ..." (*Examiner's Answer pg 3, last sentence).* The Applicants disagree.

First, the Examiner has made an inferential leap that is not justified. The '059 Gosselin et al. does not state that Example I is performed using a sterile leukotriene solution, as the Examiner argues. The following is an exact passage from Example I:

> When indicated, EBV-infected PBMC were simultaneously treated with different concentrations of LTB_4, i.e., 0.3, 3.0 and 30 nM, respectively.

'059 Application To Gosselin et al., pg. 13, ln 13-15. Further, the Examiner is reminded that Example I does not state that the peripheral blood mononuclear cells (PBMC) were cultured under sterile conditions. Consequently, the Applicants fail to see how the Examiner can justify concluding:

> Therefore, Gosselin et al. were in possession of sterile solutions of leukotrienes because they used these solutions in cell culture AND kept the cell culture alive for at least seven days, indicating that the experiment was ... intended to be performed under aseptic conditions.

Examiner's Answer pg 4, ln 14-17. The Applicants point out that the Examiner is only assuming that the PBMC cell culture was performed under sterile conditions. The phrase "intended to be performed" is an inherent admission by the Examiner that whether or not Gosselin et al. performed sterile cell culture technique is unknown. Again, the Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. In re Rijckaert, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art."). Consequently, the '441 Gosselin et al. is not prior art for this claim element.

Even if the '441 Gosselin et al. teaches "sterile cell culture technique" (which it does not), one skilled in the art would not look to cell culture media as a basis for formulations for human treatment (i.e., '441 is not pertinent art). The Federal Circuit has defined pertinent art using a "problem solving" approach. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.* 758 F.2d 613, 620, 225 USPQ 634, 638 (Fed. Cir. 1985), *cert dismissed*, 474 U.S. 976 (1985)("The jury was correctly advised to look first to the nature of the problem confronting the inventor. ... If the reference is not within the field of the inventor's endeavor, one looks at whether the field of the reference is reasonably pertinent to the problem the inventor is trying to solve."). Here, Applicants solve a problem related to clinical therapeutics, whereas the reference teaches methods related to basic laboratory procedure. Therefore, the Examiner does not present a proper U.S.C §103(a) rejection.

B. The '059 Gosselin et al. Does Not Disclose "An Aerosol"

The Examiner repeats the argument that "The Gosselin et al. patent discusses aerosols at Col 11, line 32." *Examiner's Answer, pg 5 ln 10-11.* The Examiner has not rebutted the Applicants' assertion in the Appeal Brief that "The '059 application does not teach any aerosol ..." *Applicants' Appeal Brief, pg. 8, last sentence.* In fact, the Examiner's entire argument

regarding aerosols is based upon the '441 Gosselin et al. Consequently, the Examiner's arguments are moot because they do not have the necessary priority date support necessary for a proper prior art citation. Consequently, the '441 Gosselin et al. is not prior art for this claim element.

C. The '059 Gosselin et al. Application Does Not Disclose LTC_4, LTD_4, or LTE_4

The Examiner reasserts the argument that the definition of an "LTB_4 agent" in '441 Gosselin et al. includes, LTC_4, LTD_4, and LTE_4 thereby making the Applicants' presently claimed embodiment allegedly obvious. The Applicants disagree. The Applicants point out that the '059 Gosselin et al. does not contain this paragraph to which the Examiner is referring. In fact, all the examples for an "LTB_4 agent" within the '059 Gosselin et al. refer to LTB_4 derivatives. The Examiner is requested to take note that col 6 ln 46 – col 7 ln 55 is all new matter. Consequently, the "LTB_4 agent" examples contained within these new '441 Gosselin et al. paragraphs do not enjoy the '059 Gosselin et al. priority date and cannot be maintained as prior art for this claim element.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants' Claims 22-25 and 27-37 should be passed to allowance. Appellants ask that the Board reverse the Examiner and send the case on for disposition consistent with the above.

Respectfully submitted,

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Dated: August 16, 2005

By: _____
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